Name of the combination	Rationale
	side effects of Levodopa are markedly eliminated. The combination facilitates reaching the effective level of Levodopa in the brain, the diurenal variations in control of symptoms by Levodopa are reduced by concomitant use of Benserazide and percentage of patients improved with the combination is more than with levodopa alone.
4 Levamisole with Mebendazole Tablets.	The concomitant use of both the drugs was considered necessary by experts for mixed infections of thread worm and round worm.
5. Tinidazole with Diloxanide Fuorate Tablets	The combination was cleared on the rationale that while Diolocanide is a specific locally acting anti-amoebic drug, Tinidazole is a systemic anti-amoebic and therefore a concomitant use takes care of both intestinal and extra-intestinal amoebiasis.
6. Ibueprofen with Paracetamol Tablets	While Ibueprofen is more of a anti-inflammatory and anti-rheumatic drug, Paracetamol alleviates the pain associated with inflammation. The experts consulted opined that such a combination would be useful. It is marketed in developed countries.
7. Acebutolol Hydrochloride with Hydrochlorothiazide Tablets .	Acebutolol, a beta-blocker and Hydrochlorothiazide a diuretic are allowed to be marketed in the country. Permission to market the combination was granted as the experts considered that very often combination of a beta-blocker and a diuretic is a therapeutic necessity and for better compliance their concomitant use should be allowed.
8. Betamethasone Dipropionate with Betamethasone Sodium Phosphate Injection	Both are salts/ester of Betamethasone and the combination is backed by a sound rationale to the effect that while one acts immediately the other by virtue of longer duration of action maintains the desired effects.

Monitoring of dangerous side effects of drugs

2126. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what arrangements have been made by Government for monitoring the dangerous side effects of drugs and combination of drugs;

(b) what is the set up of such cell and the details of authority who is incharge;

(c) the names of drugs and combination of drugs whose dangerous effects have come to Government's notice since last two years;

(d) whether any of those drugs have been banned;

(e) if so, the details thereof;

(f) whether Government are aware of the number of reports regarding dangerous effects of combination of Aspirin, Paracetamol with Anti-histamine published through-out the world; and

(g) if so, the details of reports which have come to Government's notice and the action taken to prevent bad effects?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) The dangerous side effects of drugs and combination of drugs are monitored through the information obtained from international organisations like World Health Organisation and through various scientific journals and literature. This is a continous process.

(b) A sub-Committee of the Drugs Consultative Committee, which is a statutory body under the Drugs and Cosmetics Act, has been constituted to monitor periodically the drugs and combinations moving in the market from the angle of rationality, side-effects/harmfulness. The sub-committee constitutes medical experts, representatives from some State Drugs Control Authorities and representative from the Central Drugs Standard Control Organisation. Medical experts from various disciplines are also co—opted. The constitution of the sub-committee is given in the enclosed statement-I. (*See below*).

(c) to (e) Statement-II regarding the names of drugs and drug combinations whose dangerous effects have come to the notice of the Government since last two years and their details including the action taken by the Government is enclosed. (*See below*).

(f) The dangerous side effects of combination of Aspirin, paracetamol with Anti—histamins have not been reported to the Government.

(g) Does not arise.

Statement—I

Constitution of the Sub-Committee appointed by the Drugs Consultative Committee

1.	Dr. M.A. Patel Director, Food and Drug Admn. *Gujarat.*	Chairman
2.	Prof. (Dr.) J. Das, Director, Drug Control, *West Bengal*	Member
3.	Shri S.S. Kattishettar Drug Controller, *Karnataka*	Member
4.	Shri C. Gopalkrishna Murty Director, Drug Control Admn. *Andhra Pradesh*	Member
5.	Dr. J.L. Kaul, Deputy Drug Controller, *Delhi Administration.*	Member
6.	Shri S.D. Bhirud, Commissioner, Food and Drug Admn. *Maharashtra State*	Member
7.	Dr. P. Das Gupta, Deputy Drug Controller (India)Dte. General of Health Services, *New Delhi*	Member (Convenor

Statement—II

Names of drugs whose dangerous side effects have come to the notice of the Government during the last two years and action taken on them

Name of the drug and countries where withdrawn	Reason for withdrawal	Action taken by us
1. Feprazone (U.K.) Germany Non steroidal anti inflammatory agent.	on accout of benefit risk consideration.	Application to market the drug received but the drug is *not approved.*
2. Fenclefenac Non-steroidal anti-inflammatory agent (U.K.)	On Account of adverse drug reactions.	Application to market the drug *not received.*
3. Propanidid (Italy Germany)	The solubilizing agent Cremaphor EL (Polyyoxyot-hylated caster oil) used in some parteral preparations. has been withdrawn. As propanidid contained the the sulubilizing agent Cromophor EL, the product has been withdrawn world-wise by the manufacturer M/s Bayer, Germany.	In India also the firm has *withdrawn* the drug propanidid and the drug is no longer being marketed in the country.
4. Nitrofazole (Germany) (Austria) for treatment of alcoholism	On account of its potential to induce liver damage.	*Application* to market the drug filed by the firm has been *withdrawn.*
5. Zomepirace Sodium (U.S.A—, Egypt, Thailand Belgium, UK) Analgesic	On account of reports of fatal anaphylactic reactions.	Application to market the drug received but the drug is *not* approved.
6. Prasterone (USA) weight reduction enhanced sexual function and extension of life.	On grounds of lack of information on the efficacy and safety on long term use.	*Not approved.*
7. Molsidomine (Austria) Vasodilator	On grounds of tumors of nasal cavity developed during long term toxicity studies in mice.	Application to market the drug received but the the drug is *not* approved.

Prevalence of fatal disease in the Country

2127. SHRI RAJNI RAJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what is the estimated numaber of persons suffering from major diseases such as Filaria, Malaria, Enteric Fever, Dysentery and Gastro—enteritis in the country as on 31st October, 1986;

(b) whether it is a fact that medicines for the treatment of these diseases are in short supply; and

(c) if so, what steps have been taken in this direction?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) According to the information received from the States/Union Territories,